



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,070	05/17/2001	Rupert Donald Holms	GJE-67	3703
23557	7590	03/03/2004	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION 2421 N.W. 41ST STREET SUITE A-1 GAINESVILLE, FL 326066669			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

55

Office Action Summary

Application No.

09/856,070

Applicant(s)

HOLMS, RUPERT DONALD

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-34, 36, 50-62, 65 and 66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-34, 62, 65 and 66 is/are rejected.
- 7) ☒ Claim(s) 36 and 50-61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 31-34, 36, 50-62 and 65-66 are pending.

Applicants' amendment filed December 15, 2003 is acknowledged, and applicants' response has been fully considered. Claims 31-34, 36, 50-62 and 65-66 have been amended, and claims 63 and 64 have been cancelled. Thus, claims 31-34, 36, 50-62 and 65-66, and SEQ ID NOs: 2 and 16-27 are examined.

Sequence Listing

2. The substitute sequence listing filed December 15, 2003 is acknowledged.

Objection Withdrawn

3. The previous objection to the disclosure at page 3, last paragraph, is withdrawn in view of applicants' amendment to the specification in the amendment filed December 15, 2003.

Rejection Withdrawn

Claim Rejections - 35 USC § 101

4. The previous rejection of claims 31-34, 36 and 50-61 under 35 U.S.C. 101, is withdrawn in view of applicants' amendment to the claim, and applicant's response at page 8 of the amendment filed December 15, 2003.

Claim Rejections - 35 USC § 112

5. The previous rejection of claims 62-66 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicants' amendment to the claim, and applicant's response at pages 8-9 of the amendment filed December 15, 2003.

Art Unit: 1653

6. The previous rejection of claims 31-33 and 62-66 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claim, and applicant's response at page 9 of the amendment filed December 15, 2003.

Claim Rejections - 35 USC § 102

7. The previous rejection of claims 50-53, 55, 57, 59 and 60 under 35 U.S.C. 102(b) as being anticipated by Gould *et al.* (The EMBO Journal 8, 4133-4141 (1989)), is withdrawn in view of applicants' amendment of the claim in the amendment filed December 15, 2003.

8. The previous rejection of claim 50 under 35 U.S.C. 102(b) as being anticipated by Holms (US Patent 5,773,573), is withdrawn in view of applicants' amendment of the claim in the amendment filed December 15, 2003.

9. The previous rejection of claims 36 and 50 under 35 U.S.C. 102(e) as being anticipated by Arpin *et al.* (U.S. Patent 6,399,584, filed on March 18, 1998), is withdrawn in view of applicants' amendment of the claim in the amendment filed December 15, 2003.

Claim Objections

10. Claim 66 is objected to because the claim contains non-elected sequences, e.g., SEQ ID NOs:3-12.

In response, applicant indicates claim 66 has been amended to delete the non-elected sequences, however, the non-elected sequences such as SEQ ID NOs:3-12 are still contained in the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1653

11. Claims 62, 65 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 62, 65 and 66 are indefinite because of the use of the term "HIV". The term "HIV" renders the claim indefinite, it is unclear what the term represents. A fully spelled out word should be indicated in the first occurrence. Claims 65 and 66 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claims 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Gould *et al.* (The EMBO Journal 8, 4133-4141 (1989)).

Gould *et al.* teach the cloning of a human ezrin and the protein sequence derived from the nucleotide sequence of the cDNA and from partial direct protein sequencing, where the protein sequence contains EREKEQMMREKEELMLRLQDYEEKTKKAERELSEQIQRALQ (residues 333-373; Fig. 1, page 4134), which comprises the hepreceptor binding sequences such as EREKE (SEQ ID NO:16), EREKEQMMREKEELML (SEQ ID NO:17), KEELM (SEQ ID NO:18) or KEELMLRLQDYEE (SEQ ID NO:19), thus the protein sequence meets the criteria of the claims (claim 31-34).

In response, applicants indicate the cited reference only describe the sequence of entire ezrin protein, it does not disclose or suggest the particular claimed peptides, which are the sequences of SEQ ID NO:29 or at least 5 consecutive amino acids thereof (pages 9-10 of the response). The response has been fully considered, however, the argument is not found persuasive because the claim recites a molecule which “comprises” a hepreceptor binding sequence, wherein the hepreceptor binding sequence is the sequence of SEQ ID NO:29 or at least 5 consecutive amino acids thereof, thus the ezrin protein comprising the hepreceptor binding sequence such as SEQ ID NO:16, 17, 18 or 19 anticipates the claims.

13. Claims 31-34, 62, 65 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Holms (US Patent 5,773,573).

Holms teaches a purified peptide, TEKKRRETVEREKE (HEP1) based on human ezrin (column 1, lines 61-65; column 3, lines 49-50), which comprises the hepreceptor binding sequences such as EREKE (SEQ ID NO:16), thus the peptide meets the criteria of the claims (claim 31-34). The reference also teaches orally administered HEP1 to HIV infected patients in an amount reduced viral load by 46% as measured by p24Ag, and reduced the infectivity of HIV

Art Unit: 1653

by 16 X as measured TCID and the effect persisted for 7 days after the treatment, which suggests that a T suppressor cell population has been induced in the patient which reduces infectivity of HIV and immune activation (Example 2; column 14, lines 43-58; Fig 2; claims 62, 65 and 66).

In response, applicants indicate the 573' patent does not disclose or suggest the specific claimed peptides, and the claims in the present application do not encompass the peptide of the 573' patent (page 10 of the response). The response has been fully considered, however, the argument is not found persuasive because the 573' patent discloses the peptide of TEKKRRETVEREKE (HEP1) which contains a hepreceptor binding sequence EREKE (SEQ ID NO:16), and the claim recites a molecule which "comprises" a hepreceptor binding sequence such as EREKE, thus HEP1 anticipates the claims.

14. Claims 31-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Arpin *et al.* (U.S. Patent 6,399,584, filed on March 18, 1998).

Arpin *et al.* teach the amino acid sequence of ezrin, which contains EREKEQMMREKEELMLRLQDYEEKTKKAERELSEQIQRALQ (residues 333-373; Fig. 1A, SEQ ID NO:1 of the patent), which comprises the hepreceptor binding sequences such as EREKE (SEQ ID NO:16), EREKEQMMREKEELML (SEQ ID NO:17), KEELM (SEQ ID NO:18) or KEELMLRLQDYEE (SEQ ID NO:19), and the sequence of RQIKIWFQNRRMKWKKLRLQDY(p)EEKTK (SEQ ID NO:2 of the patent; column 3, lines 1-3), which comprises QDY(p)EE (SEQ ID NO:27), thus the protein of ezrin and the peptide meets the criteria of the claims 31-34.

In response, applicants indicate the 584' patent teaches the mutant sequences of ezrin, it does not disclose or suggest the specific claimed peptides (pages 10-11 of the response). The

Art Unit: 1653

response has been fully considered, however, the argument is not found persuasive because the 584' patent discloses the ezrin protein and the peptide which contain a hepreceptor binding sequence, and the claim recites a molecule which "comprises" a hepreceptor binding sequence such as EREKE or QDY(p)EE, thus the peptides anticipate the claims.

15. Claims 36 and 50-61 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

16. Claims 31-34, 62, 65 and 66 are rejected, and claims 36 and 50-61 are objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1653

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

February 26, 2004

Christopher S. F. Low

**CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800**